



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,021	01/30/2004	Robert R. Whittle	5573-115IP7CT7	9712
20792	7590	08/22/2006		
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER GRAFFEO, MICHEL	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/769,021

Applicant(s)

WHITTLE ET AL.

Examiner

Michel Graffeo

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 27 Dec 04 (1 sht).
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Action

Claims 65-84 are examined.

Applicant has provided arguments for the patentability of claims 65-84 in the response filed 28 April 2006.

Applicant's arguments, see response, filed 28 April 2006, have been fully considered and are persuasive to the extent that the rejection under 35 USC §112, has been withdrawn. Any rejection not specifically stated in this Office Action has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The new Title submitted by Applicant is noted and accepted.

Information Disclosure Statement

Applicant's response is acknowledged but not sufficient. No references were found in the official file for US Patent Application No. 10/434259 and US Patent No. 6667321 is not a parent application of record. For these reasons and that no non-US Patent literature references are included in the file, the IDS statements other than the ISD dated 21 December 2004 (included herein), are not considered in their entirety.

Claim Rejections - 35 USC § 102

Claims 65-84 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/32957 to Astra Aktiebolag.

The WO 95/32957 reference teaches the 5-methoxy and 6-methoxy enantiomers of omeprazole (in current claims 65-84; see page 4 lines 15-25) and magnesium cations thereof in an enterically coated capsule form (in current claims 66, 69, 71, 74, 76, 79, 81 and 84; see page 9 lines 8, 17 and 20) for the inhibition of gastric acid secretion (in current claims 65-84; see page 1 lines 10-15) wherein the active agent is present in from .1 to 95% of the dosage unit (in current claims 65, 70, 75 and 80; see page 9 lines 8-10) and for example 50mg (in current claims 68, 73, 78 and 83; see page 18 Table 1) and further wherein the active agent can be either the 5- or 6-methoxy enantiomer or both since they are both made separately and/or able to be separated (see for example page 12 Example 4 wherein the 6-methoxy is made to at least 92% purity).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1614

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-68 of U. S. Patent No. 6,369,087 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Regarding the method and process claims of the patent claims, one of ordinary skill in the art would have found a process of making and a process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the processes.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-12 of U. S. Patent No. 6,262,085 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Regarding the method claims of the patent claims, one of

Art Unit: 1614

ordinary skill in the art would have found the process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the method.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-17 of U. S. Patent No. 6,706,737 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-30 of U. S. Patent No. 6,667,321 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole. Additionally, the composition comprising a cyclodextrin as claimed in the patent would

Art Unit: 1614

be obvious since cyclodextrins are commonly used as additives in pharmaceutical preparations (see cyclodextrin. The Hutchinson Encyclopedia, Helicon (2001).

Retrieved 29 December 2005, from xreferplus.

<http://www.xreferplus.com/entry/1079478>).

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-24 of U. S. Patent No. 6,444,689 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole. Regarding the method claims of the patent claims, one of ordinary skill in the art would have found the process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the method.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-5 of U. S. Patent No. 6,667,324 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common

Art Unit: 1614

subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-45 of U. S. Patent No. 6,653,329 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Although the instant application claims a pharmaceutical formulation, such would be obvious in light of the known application for omeprazole. Regarding the process claims of the patent claims, one of ordinary skill in the art would have found a process of making the claimed compounds to be obvious since the compositions are the same and would have been used in the process.

Claims 65-84 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-101 of copending Application No. 10/855809. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully claimed in the referenced copending application and would be covered by any patent granted on that

Art Unit: 1614

copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole. Regarding the method and process claims of the patent claims, one of ordinary skill in the art would have found a process of making and a process of using the claimed compounds to be obvious since the compositions are the same and would have been used in the processes. Although the instant application does not specifically recite the coordination complex claimed in the reference application, products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable notwithstanding the method of identification or condition of the chemical. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present even though the method of identification may be different.

Response to Arguments - 35 USC § 112

Applicant's arguments filed 28 April 2006 have been fully considered and are persuasive for the reasons of record.

Response to Arguments - 35 USC § 102

Applicant's arguments filed 28 April 2006 have been fully considered but they are not persuasive. Applicant argues that the WO 95/32957 reference does not teach the active agent in "pure form" but instead teaches ethyl carbonate derivatives of the active

Art Unit: 1614

agent. That notwithstanding the WO 95/32957 reference does also teaches optically pure forms of the active agent (see in particular lines 23-26 on page 3). Absent any definition in the Specification to the contrary, the reference teaches the compound in "pure" form and a formulation "comprising" the active ingredient. Therefore, the reference teaches each limitation of the claimed formulation.

Response to Arguments – Double Patenting

Applicant's arguments filed 28 April 2006 have been fully considered and the Examiner notes that the Applicant intends to file terminal disclaimers upon indication from the Office that the pending claims are allowable. Until that time, the rejection will be maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1614

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

15 Aug 2006
MG



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER